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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,880	05/14/2001	Robert S. Chapkin	P01592US2	9477

7590

05/27/2003

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,880

Applicant(s)

CHAPKIN ET AL.

Examiner

Jehanne E Souaya

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 34-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/2001.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Currently, claims 34-49 are pending in the instant application. Claims 1-33 have been cancelled.

Priority

2. It is noted that the instant application claims priority from application 09/381,086, filed 9/14/1999, which was a CIP of PCT/US98/06698 which claimed priority from 60/043,048, filed 4/4/1997. The currently pending claims have been awarded priority to the '086 application.

Therefore, the effective filing date of the currently pending claims is 9/14/1999.

PCT/US98/06698 and 60/043,048 did not teach or suggest determining the expression of PKC isozymes in colonocytes from rectal vault eluate.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 34-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al (hereafter referred to as Davidson; Carcinogenesis, vol. 19, pp 253-257; Feb. 1998) in view of Sidransky (US Patent 5,935,787) and Boley, S.J. (Surgery, Gynecology and Obstetrics, vol. 159, 1984; pp 481-484).

The claims are drawn to methods of determining the expression of PKC isozymes in colonocytes of a patient, detecting colonic biomarkers, or screening for colon cancer in a patient, by isolating polyA+ RNA from rectal vault eluate containing sloughed colonocytes and assaying the isolated poly A+ RNA and determining the level of mRNA encoding PKC isozymes PKC ζ and/or β II, (or PKC ζ and β II for methods of screening for colon cancer).

Davidson teaches a method of utilizing feces containing sloughed colonocytes as a sensitive technique for detecting diagnostic colonic biomarkers PKC ζ and β II by isolating sloughed colonocytes from feces and assaying the poly A+ RNA for the level of mRNA encoding PKC ζ and β II (see abstract, and 254, col 1). Davidson specifically teaches determining the isozyme ratio between PKC ζ and β II (see abstract; instantly pending claims 36,42, and 47). Davidson specifically teaches using primers identical to SEQ ID NOS 7- 8 and 11-12 of the instantly pending claims in RTPCR to determine mRNA levels (p. 254; see col. 2, primers for PKC ζ internal standard and PKC β II internal standard; instantly pending claims 39, 44, and 49). Davidson teaches that the isozyme ratio was strongly related to tumor incidence (see p. 255, col. 2) and teaches comparing levels with animals with and without tumors (instantly pending claims 37-38; 43, and 48).

Davidson does not teach detecting isolating poly A+ RNA from sloughed colonocytes from rectal vault eluate, however Sidransky teaches that nucleic acids corresponding to hypermutable mutations associated with neoplasia can be extracted from any bodily fluid that drains the organ (see col. 4, lines 17-40). As the claims do not make clear what is encompassed by 'rectal vault eluate' and the specification does not define the term rectal vault eluate, nor did a thorough search of prior art and patent databases reveal any definitions for "rectal vault eluate" the term has been broadly interpreted to encompass fecal fluid, which was known to exist at the time the invention was made (see Boley, "summary"), or liquid fecal matter. Such fecal fluid or liquid fecal matter is fluid that drains from the colon and rectal vault. Further, as fecal matter was known at the time of the invention to contain sloughed colonocytes, the ordinary artisan would expect that fluid in contact with the rectal vault and fecal matter, such as fecal fluid or liquid fecal matter, would also contain sloughed colonocytes. Given that Sidransky teaches that nucleic acids corresponding to neoplasia can be extracted from bodily fluid that drain the organ, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, to use the method of Davidson to detect PKC colonic biomarkers, or screen for colon cancer using fecal fluid or liquid fecal matter. The ordinary artisan would have had a reasonable expectation of success that poly A+ RNA from sloughed colonocytes could be obtained from fecal fluid or liquid fecal matter in contact with either the rectal vault or feces, as the art teaches that sloughed colonocytes extracted from feces could be used in the method of Davidson and Sidransky teaches that nucleic acids corresponding to neoplasia can be extracted from bodily fluid that drain the organ. The ordinary artisan would have been motivated to use the method of Davidson to detect PKC colonic biomarkers, or screen for colon cancer using fecal fluid or liquid

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fecal matter because the ordinary artisan would have recognized that such was a readily accessible equivalent method of isolating sloughed colonocytes that could then be used to detect PKC colonic biomarkers, or screen for colon cancer, and further because Davidson teaches that the method using fecal matter was a sensitive technique for detecting colonic biomarkers. It is noted that the preamble states "invasively", however the positive process steps of the method do not indicate that the steps are either invasive or make clear what is encompassed by 'rectal vault eluate', accordingly, the preamble recitation of "invasively" has been given no patentable weight.

Conclusion

6. No claims are allowable over the cited prior art.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634

5/20/03